REMARKS

Claims 21, 22, 28, 29, and 36-39 are pending. Claims 21, 22, 28, 29, and 36-39 are amended herein. Accordingly, amended claims 21, 22, 28, 29, and 36-39 are presently under consideration.

Support for amendment to the claims is found throughout the specification and in the original claims. Specifically, support for amendment to claims 21, 28, and 36-38 is found, for example, in paragraphs 20-28 and 32 of the specification. Support for amendment to claims 22, 29, and 39 is found, for example, in paragraph 11, and Table 1 of the specification. No issue of new matter is introduced by these amendments.

Rejections under 35 U.S.C. § 112

Claims 22, 29, and 39 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Claims 22, 29, and 39 are amended herein to clarify the subject matter. In view of the amendments to the claims, this rejection, as it applied to claims 22, 29, and 39 is obviated.

In view of the amendments to the claims, Applicant respectfully requests reconsideration and withdrawal of the rejection of the claims under 35 USC § 112, second paragraph.

Rejection Under 35 U.S.C. § 102

Claims 21, 22, 28, 29, 36, and 37 stand rejected and newly added claims 38 and 39 are rejected under 35 U.S.C. §102(e) as allegedly anticipated by Meeker et al. (United States Pub No. 2002/0095135). Claims 21, 22, 28, 29, and 36-39 are amended herein to clarify the subject matter of the claims. In view of the amendments to the claims and Applicant's arguments presented herein, the rejection as it applied to claims 21, 22, 28, 29, and 36-39 is respectfully traversed.

The claims are amended herein to specify that the method consists of administering NB-DNJ (claims 21, 28, 36, and 37) or NB-DGJ (claim 38) to a patient afflicted with a mucopolysaccharidosis (MPS) disease. As previously stated, United States Pub No. 2002/0095135 (Meeker et al.) is directed to combination therapy. A directive to combination therapy is evidenced throughout the specification. The Examiner's attention is respectfully

directed to paragraphs [0041]-[0045], [0064], and [0066]-[0067], which attest to a combination therapy approach. The following passage (paragraph [0030]) excerpted from Meeker et al. also typifies this approach:

"This invention provides various combinations of enzyme replacement therapy, gene therapy, and small molecule therapy for the treatment of lysosomal storage diseases. According to the invention, several general approaches are provided. Each general approach involves ***combining at least two*** *of enzyme replacement therapy (ERT), gene therapy (GT), and small molecule therapy (SMT) in a manner which optimizes clinical benefit while minimizing disadvantages associated with using GT or ERT or SMT alone."* Emphasis added.

That being the case, Meeker et al. do not teach a therapeutic approach that calls for administration of only small molecule therapy (e.g., imino sugar inhibitors of glucosylceramide synthase) for the treatment of any lysosomal storage disease. Meeker et al. teach combination therapy. By extension, therefore, Meeker et al. also fail to teach a therapeutic approach directed to administration of only imino sugar inhibitors of glucosylceramide synthase for the treatment of mucopolysacccharidosis diseases.

In view of the above, United States Pub No. 2002/0095135 does not teach the instant method. The rejection, as it applied to claims 21, 22, 28, 29, and 36-39, is therefore respectfully traversed. Reconsideration and withdrawal of the rejection are, therefore, deferentially requested.

Claims 21, 28, and 36-38 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Dwek et al. (WO 00/62779). Claims 21, 28, and 36-38 are amended herein to clarify the subject matter of the claims. In view of the amendments to the claims and Applicant's arguments presented herein, the rejection as it applied to claims 21, 28, and 36-38 is respectfully traversed.

The claims are amended herein to specify that the method consists of administering NB-DNJ (claims 21, 28, 36, and 37) or NB-DGJ (claim 38) to a patient afflicted with a mucopolysaccharidosis (MPS) disease. As indicated throughout the WO 00/62779 application, Dwek et al. teach a combination therapy. This is evident in the first, second, third, fourth, and fifth aspects of the invention described in the WO 00/62779 application.

More specifically, the first, second, and third aspects relate to use of an inhibitor of glycolipid synthesis and an agent capable of increasing the rate of glycolipid degradation in the manufacture of a medicament. The fourth aspect pertains to a product comprising an inhibitor of glycolipid synthesis and an agent capable of increasing the rate of glycolipid degradation as a combined preparation. The fifth aspect calls for a pharmaceutical composition comprising an inhibitor of glycolipid synthesis and an agent capable of increasing the rate of glycolipid degradation. See, for example, page 4, lines 4-7; page 5, lines 14-17; page 6, lines 9-12; page 6, lines 14-17; and page 6, lines 25-27. Other aspects of the invention described therein are directed to methods for the treatment of a relevant disorder involving combined administration of an inhibitor of glycolipid synthesis and an agent capable of increasing the rate of glycolipid degradation, as detailed at page 7, lines 5-18. That being the case, Applicant asserts that Dwek et al. do not teach a therapeutic approach that calls for administration of only imino sugar inhibitors of glucosylceramide synthase for the treatment of mucopolysacccharidosis diseases.

In light of the above, the WO 00/62779 application fails to teach the instant method. The rejection, as it applied to claims 21, 28, and 36-38, is therefore respectfully traversed. Reconsideration and withdrawal of the rejection are, therefore, deferentially requested.

In view of the amendments to the claims and the above arguments, the Examiner is respectfully requested to reconsider the validity of the rejection of claims under 35 U.S.C. §102 and withdraw the rejection.

Rejections under 35 U.S.C. § 103

Claims 22, 29, and 39 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Dwek et al. (*supra*), as applied to claims 21, 28, and 38, further in view of Danos et al. (Mol. Cell. Biol. Hum. Dis. 5:530-567, 1995). Claims 21, 22, 28, 29, and 36-39 are amended herein to clarify the subject matter. In view of the amendments to the claims and arguments presented herein, the rejection, as it applied to claims 22, 29, and 39, is respectfully traversed.

The instant claims are amended to specify that the method consists of administering NB-DNJ (claims 21, 28, 36, and 37) or NB-DGJ (claim 38) to a patient afflicted with a mucopolysaccharidosis (MPS) disease. As detailed above, the WO 00/62779 application teaches only combination therapy, medicaments, and pharmaceutical compositions. This is

apparent in all of the aspects of the invention described in the WO 00/62779 application. See, for example, page 4, lines 4-7; page 5, lines 14-17; page 6, lines 9-12; page 6, lines 14-17; page 6, lines 25-27; and page 7, lines 5-18. In light of the above, it is apparent that Dwek et al. have no appreciation of a therapeutic approach directed to administration of only imino sugar inhibitors of glucosylceramide synthase for the treatment of mucopolysacccharidosis diseases. Dwek et al., therefore, fail to teach the instant method.

The Examiner recognizes that Dwek et al. do not specifically identify the MPS conditions recited in claims 22, 29, and 39. The Examiner relies on Table 17.1 of Danos et al. which shows that the various conditions recited in the claims were recognized in the art as mucopolysaccharidoses at the time the Dwek et al. application was published. Responsive thereto, Applicant asserts that although Danos et al. do teach various conditions recognized as mucopolysaccharidoses, this reference fails to remedy the defects of Dwek et al. with respect to the instant claims. Neither of these references teaches or suggests a therapeutic approach directed to administration of only imino sugar inhibitors of glucosylceramide synthase for the treatment of mucopolysacccharidosis diseases. Moreover, the combined teachings of these references also fail to teach administration of only imino sugar inhibitors of glucosylceramide synthase for the treatment of mucopolysacccharidosis diseases. Thus, a skilled practitioner would not be motivated to arrive at the present invention after reading Dwek et al. and Danos et al. Indeed, Dwek et al. teaches away from the present invention because this reference is focused in its entirety on combination therapy. In light of the above, Dwek et al. and Danos et al. fail to provide the guidance necessary to envision the present invention and would, in fact, lead a skilled practitioner to attempt an alternative method involving combination therapy. In view of the amendments to the claims and arguments presented herein, the rejection, as it applied to claims 22, 29, and 39, is therefore respectfully traversed.

In light of the above, reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. §103 is deferentially requested.

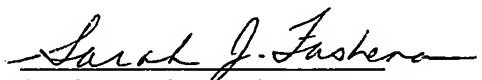
Fees

No additional fees are believed to be necessitated by this amendment. However, should this be an error, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment or to credit any overpayment.

Conclusion

It is submitted, therefore, that the claims are in condition for allowance. No new matter has been introduced. Allowance of all claims at an early date is solicited. In the event that there are any questions concerning this amendment, or application in general, the Examiner is respectfully urged to telephone the undersigned so that prosecution of this application may be expedited.

Respectfully submitted,



Sarah J. Fashena, Ph.D.
Agent for Applicant(s)
Registration No. 57,600

KLAUBER & JACKSON
411 Hackensack Avenue
Hackensack, New Jersey 07601
(201) 487-5800

December 6, 2007

Enclosures: Petition for a One Month Extension of Time